

**REMARKS**

Claims 1–24 and 28–33 are pending in this application. Non-elected claims 8 and 21–24 have been withdrawn from consideration by the Examiner. By this Amendment, claims 1, 13, 30, and 32 are amended, and claim 33 is added. Support for the amendments to the claims may be found, for example, in the original claims and specification. No new matter is added.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

**I. Claim Objections**

The Office Action objects to claim 30 for an informality. Claim 30 is amended to obviate the objection. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

**II. Rejection under 35 U.S.C. §112, Second Paragraph**

The Office Action rejects claims 13 and 14 as being indefinite under 35 U.S.C. §112, second paragraph. By this Amendment, claim 13 is amended to obviate the rejection. Accordingly, reconsideration and withdrawal of the rejection are requested.

**III. Rejections Under 35 U.S.C. §103**

**A. Illum**

The Office Action rejects claims 1–3, 9–13, 16–20, 28, 29, 31, and 32 under 35 U.S.C. §103(a) over U.S. Patent No. 4,904,479 to Illum (hereinafter "Illum"). Applicants respectfully traverse the rejection.

Claim 1, before being amended as set forth above, required that the hydrophobic groups of the hyaluronan-based coating composition are "anchored in the polymeric core of the particle." Despite the Office Action's assertions, Illum does not disclose this feature.

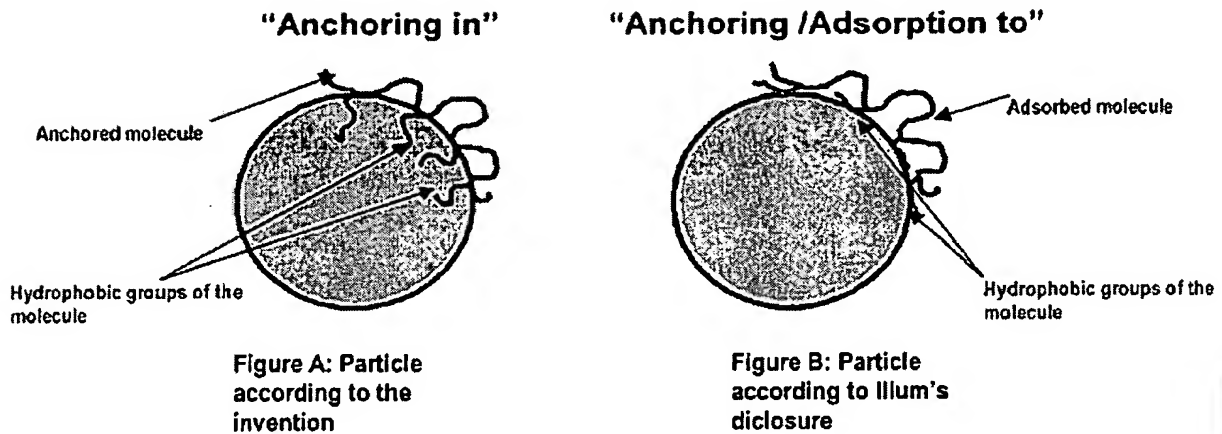
The Office Action appears to fail to appreciate the subtle but substantial difference between Applicants' claimed subject matter as viewed in light of the specification, and the disclosure of Illum. For example, Applicants' specification explains on page 10:

When the organic solvent is evaporated off, the amphiphilic hyaluronan derivatives remain advantageously attached at the surface of the particles thus formed, the hydrophobic groups being anchored more or less deeply in the organosoluble polymer core forming the particles, and the hydrophilic component, mainly corresponding to the hyaluronan backbone, being exposed at the surface.

Emphasis added. Thus, Applicants' specification teaches that the hydrophobic groups are anchored in the polymer core. On the other hand, Illum only makes reference to the anchoring or adsorption of the molecules to the surface of a particle:

<u>Cite</u>	<u>Passage</u>
Column 2, line 21	"... adsorbed layer ..."
Column 2, lines 27-30	"The hydrophobic domain will anchor the coating to the particle surface."
Column 3, lines 19-21	"... the importance of anchoring the polymer coating to the surface of the particle and surface layer thickness."
Column 3, lines 53-54	"... adsorbed material ..."
Column 4, line 53	"... adsorbed layer thickness ..."
Column 5, line 6-7	"... adsorbed layer thickness ..."
Column 5, lines 33-34	"... adsorbed layer thickness ..."

The figures below schematically show the differences between the anchoring of hydrophobic groups of a hyaluronan molecule in a particle core (Figure A) and the anchoring of hydrophobic groups of a hyaluronan molecule to a particle surface (Figure B).



These molecules are structurally different because the hydrophobic groups of the hyaluronan extend in the particle core as depicted in Figure A, whereas the hydrophobic groups of the hyaluronan cover the outside surface of the particle core as depicted in Figure B.

The methods for producing the claimed molecules are very different from the methods taught by Illum for producing its molecules. As explained in Applicants' specification, the anchoring of the hydrophobic groups in the particle core takes place during the formation or production of the particles, wherein the amphiphilic hyaluronan is used as a surfactant for stabilizing the emulsion that is used for producing the particles. *See* specification, page 9, line 24 to page 11, line 3. The anchoring of the hydrophobic groups in the particle core is sufficient to secure the hyaluronan to the particle.

On the other hand, Illum discloses a method in which the molecules are adsorbed onto the particle surfaces after the production of the particle, and are therefore not anchored in the particle core during the production of the particles. *See, e.g.*, column 3, lines 31–33; and column 5, lines 32–34. Illum also discloses attachment of suitable hydrophilic groups to particles by surface grafting techniques either during the polymerization process where the particles are produced initially, or by subsequent grafting methods involving ultraviolet light and gamma irradiation. *See* column 10, lines 57–62. Because surface grafting is a chemical modification of the particle surfaces (see the attached definition from the Academic Press

Dictionary of Science and Technology), Illum does not disclose a process that results in the hydrophobic groups being anchored in the particle but rather to the particle surface.

Moreover, the anchoring of the molecules to the particle surface is not sufficient to secure the molecules to the particle, and the particle should be coated with protein or gelatin so as to retain the molecules on the particle according to the disclosure of Illum:

<u>Cite</u>	<u>Passage</u>
Column 2, line 27-30	"... prevent its [coating] displacement [to the particle surface] by plasma proteins ..."
Column 7, lines 34-35	"... some of the gelatin is adsorbed onto the surface of the particles ..."

Attached herewith is a Declaration under 37 CFR §1.132 by one of the inventors, Edith Dellacherie. The Declaration presents technical reasons as to why the claimed invention cannot be obtained by the process taught by Illum. The Declaration also states that the methods taught in the Applicants' specification is the only method known to the Declarant for obtaining the claimed molecules where the hydrophobic portions are anchored in the core of the particles and not on the surface of the particles.

For at least the reasons discussed above, Applicants respectfully submit that the rejection is in error because the feature of the hydrophobic groups of the hyaluronan-based coating composition being "anchored in the polymeric core of the particle" describes a structural feature that is distinct from the molecules taught by or otherwise obtainable from the disclosures of Illum. Nevertheless, to ensure that the claim is being interpreted correctly, claim 1 is amended to recite "the hydrophobic groups are anchored and extend at least in part in the polymeric core of the particle." Applicants respectfully submit that if the amendments and Declaration do not result in an allowance, the next Office Action should not be made Final because any such rejections would not have been necessitated by these amendments to claim 1.

Illum would not have rendered obvious claim 1. Claims 2, 3, 9–13, 16–20, 28, 29, 31, and 32 variously depend from claim 1 and, thus, also would not have been rendered obvious by Illum. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

**B. Illum, della Valle, McMurry**

The Office Action rejects claims 4–7 under 35 U.S.C. §103(a) over Illum in view of U.S. Patent No. 4,851,521 to della Valle et al. ("della Valle"), and further in view of J. McMurry, Organic Chemistry, 3<sup>rd</sup> Ed. ("McMurry"). Applicants respectfully traverse the rejection.

The Office Action provides no suggestion or basis for concluding that della Valle and McMurry cure the above-noted deficiencies of Illum with respect to claim 1. Accordingly, claims 4–7 are patentably distinct from the asserted combination of Illum, della Valle, and McMurry at least because of their dependence from claim 1, as well as on the basis of their additional limitations. Reconsideration and withdrawal of the rejection are respectfully requested.

**C. Illum and Lee**

The Office Action rejects claims 14 and 15 under 35 U.S.C. §103(a) over Illum in view of U.S. Patent No. 5,753,234 to Lee et al. ("Lee"). Applicants respectfully traverse the rejection.

The Office Action provides no suggestion or basis for concluding that Lee cures the above-noted deficiencies of Illum with respect to claim 1. Accordingly, claims 14 and 15 are patentably distinct from the asserted combination of Illum and Lee at least because of their dependence from claim 1, as well as on the basis of their additional limitations. Reconsideration and withdrawal of the rejection are respectfully requested.

**IV. New Claim**

By this Amendment, new claim 33 is presented. New claim 33 is believed to be patentable over the applied references because of its dependence from claim 1, as well as for the additional limitations recited in claim 33. Prompt examination and allowance of new claims 33 are respectfully requested.

**V. Rejoinder**

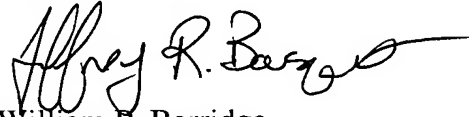
Applicants also respectfully request rejoinder of non-elected claims 8 and 21–24. Because claims 8 and 21–24 are product claims that depend from claim 1, they include all the limitations of claim 1, and are eligible for rejoinder with the elected product claims when the product claims are found allowable. *See* MPEP §821.04. Because the product claims are believed to be allowable for at least the reasons presented above, Applicants respectfully request withdrawal of the Restriction Requirement and rejoinder of claims 8 and 21–24.

**VI. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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WPB:JRB

Attachments:

Declaration under 37 CFR §1.132

Definition of "surface grafting" from the Academic Press Dictionary of Science and Technology

Date: February 22, 2010

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